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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,711	03/23/2004	Nita Mody	36554US1	2665
116	7590	05/16/2006	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,711

Applicant(s)

MODY, NITA

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,43,46,47 and 51-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,43,46,47 and 51-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received:
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 03/06/06 is acknowledged. Claims 1-34, 36-42,44-45 and 48-50 are cancelled. Claims 35, 43, 46-47 and 51-59 are pending in the application.

Response to Amendment

2. In response to the amendment the examiner modifies the grounds for rejections. Objection to the specification is sustained.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to as not containing “a written description of the invention ... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same ... in its best mode”.

It seems that the disclosure is an attempt to cover all possible embodiments involving pH indicators incorporated into single- or multi-layered matrices comprising a variety of materials from non-permeable to superabsorbent, with most of the embodiments well known in the art. Some of the embodiments, e.g. those involving “fluid barrier layers”, which are not permeable to the fluid to be detected, are not enabled, since no fluid can be detected in such layers or can get through these layers to reach another layer with the incorporated pH indicator. The variety of the embodiments covering all possible materials used for detecting or controlling biological fluids or moisture by employing pH indicators disclosed in the specification does not allow to clearly and unambiguously identify the essence of the invention and its distinction from the prior art.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 51 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim recites the first layer being impermeable to the fluids, which disables the wetness indicator, since the fluids cannot reach the pH indicator.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35, 43, 46-47 and 51-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites a first and a second ink layers. According to one definition, an “ink layer is the bottom layer of a thermal transfer ribbon which is composed of waxes, resins or a combination of both” (<http://www.integratedlabeling.com/misc/glossaryghijk.htm>). According to another definition, it is the layer comprising ink or a dye. Neither of these conventional definitions correspond a description of the “first ink layer” recited in the claim. According to claim 35, the first ink layer controls a fluid contact with at least a portion of the second ink layer. Moreover, it is not clear, what does it mean that the first layer controls the fluid contact with “at least a portion” of the second ink layer, if the first and second layers have total contact with each other? Does it mean that the first layer comprises various portions, some of which control the fluid contact with the second layer, while others don’t? Moreover, the passage reciting that “at least one of said layers contain a fluid regulating additive to regulate fluid contact with the pH indicator of the second ink layer” raises a question as to what the first ink layer controls, if the

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fluid regulating additive is contained only in the second ink layer? How can it function as the fluid controlling layer, if it does not comprise such additive? Moreover, if the second layer comprises both, the pH indicator and the fluid controlling agent, then it is completely unclear as to what is the function of the first ink layer?

Claim 47 is unclear and indefinite as to what type of a polymer it recites. Since the essence of the invention is a composition of the wetness indicator, which defines regulation of the fluid flow to the pH indicator, the origin of the polymer is essential to the invention. The lack of its definition renders the claim and all dependent claims unclear and indefinite. Moreover, it is not clear, how the amount of zeolite “effective to provide said cured or dried ink layer ... with sufficient moisture transmission” is determined, and what is considered to be “sufficient” moisture transmission?

The essence of the recitation of claim 52 is unclear. If the wetness indicator is supposed to monitor the presence of the fluid in the environment, then what is the point to make it less sensitive to this same fluid by lessening or delaying fluid contact with the second ink layer?

Claim 54 is unclear and indefinite as to what is the origin of the polymer recited in the claim, which raises the same issue as was indicated for claim 47.

Claim 55 is unclear and indefinite as to what the numbers recited in the claim are supposed to define? The material of the first and second ink layers? Describing the materials via their specific gravities does not provide a clear and definite description of the materials and therefore renders the claim unclear and indefinite.

In claim 56 it is not clear, how percentage of the pH indicating agent depends on the weight of the second ink layer? A percentage amount is already a relative amount (e.g. a weight percentage), and therefore should not depend on the weight of any of the components. The recitation of the claim is unclear and indefinite.

From claim 57 it is not clear, which molecules that are bigger than the water molecules are meant in the claim, and which specific pore sizes of zeolites meet the requirement recited in the claim?

Claim 58 has all deficiencies of the claims recited similar subject matter separately, as indicated above.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 35 and 43** are rejected under 35 U.S.C. 102(b) as being anticipated by Allan et al. (US 2001/0037101 A1).

Allan discloses a wetness indicator “comprising at least two segregated or intermixed superabsorbent polymers [SAPs], wherein each superabsorbent polymer, or one less than each superabsorbent polymer, is incorporated throughout with a latent indicator peculiar to that superabsorbent polymer so that each superabsorbent can be distinguished from each other upon development of the indicators” (page 1 [0006]). The wetness indicator can be a part of a diaper (page 1, [0015]). “Examples of suitable latent indicators include ...pH sensitive indicators (acid or base)” (page 1 [0014]). SAPs can be of high permeability and slow absorption, or of low permeability and high absorption, so that they regulate the flow of the fluid (page 1 [0003]). The combination of several portions of SAPs, part of which are intermixed and part are segregated provides at least two ink layers recited in the claims. “[0019] In FIG. 2, which is a side view illustration of another embodiment of the present invention, the insult region (12) and retention region (14) appear as stacked layers. In this embodiment, the retention region contains an SAP of high permeability and slow absorption (12), but no incorporated indicator. Only the retention region (14) contains the latent indicator (14a)” (page 2, left column”).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 46-47 and 52-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Allan in view of Furio et al. (WO 91/11977) or Guarracino et al. (US 6,096,299).

Allan does not indicate zeolite in any of two layers.

Furio et al. (WO 91/11977) and Guarracino disclose adding zeolites as odor controlling additives in any layer of multilayered bodily fluid retention articles.

It would have been obvious for any person of ordinary skill in the art to add zeolite into at least the layer without the latent indicator of Allan's wetness indicator exactly for the purpose indicated by Furio and Guarracino, i.e. to control odor of the bodily fluid. Since the molecules of biological fluids can be quite small molecules (such as amines), zeolite will have an inherent function of preventing the pH indicator leakage, since the molecules of pH indicators are bigger than odor molecules.

Selecting the polymers with weight ranges indicated in claims 55 and 58 and optimizing pH indicator weight percentage recited in claims 56 and 58 are within the skills of the ordinary person in the art.

12. **Claim 47** is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 60178362A2 or JP 05034334A (Abstracts) in view of Deffeyes (US 4,036,360).

JP 60178362A2 or JP 05034334A disclose a wetness indicating ink comprising a polymer, a pH indicating agent and a fluid regulating additive with the additive dispersed in the ink layer sufficient for the fluid to be transmitted to the pH indicator. Fluid regulating additive is a water absorbing powder.

While the abstracts of JP applications do not specify water-absorbing powder, Deffeyes indicates “among the dessicants which can be used are alumina, bauxite, anhydrous calcium sulfate, water-absorbing clays, silica gel, zeolite and any of the other moisture-absorbing materials known to the art” (col. 2, lines 23-31). Therefore, even if JP applications do not disclose specifically zeolites as water-absorbing materials, it would have been obvious for any person of ordinary skill in the art to use them as conventional water absorbing materials as taught by Deffeyes.

Response to Arguments

13. Applicant's arguments filed 03/06/06 have been fully considered but they are not persuasive.

Regarding objection to the specification, while the amendment removes non-enabled embodiments from the specification, the issues of unclarity and indefiniteness of the disclosure remain. The amended claims appear to be extracted from the specification in a piece manner to be presented in a more clear and definite form. However, the specification does not provide a clear and definite description of the invention. Fluid regulation is described as being provided with all possible materials existed - impermeable, semi-permeable, super-permeable, etc. Inhibiting fluid contact with the pH indicator as a form of a fluid control does not make any sense for a wetness indicator. Zeolites are well-known additives for diapers and other bodily fluid regulating items, with zeolites porosity inherently providing fluid regulation, specifically odor regulation, which intrinsically provides any dye leakage control.

Regarding impermeable “fluid barrier layers”, which are supposed to regulate fluid, the Applicant's arguments are not convincing. Preventing fluid contact at the area of “fluid barrier layers” results in uncontrollable contact of liquid, which does not have any place to go, with the pH indicator at all permeable areas. The essence of this embodiment is absolutely unapparent. Moreover, the wetness indicator is defined as comprising two layers, one of which is fluid regulating. How such wetness indicator is enabled, if this fluid regulating material is impermeable to the fluid? Is it enabled only for the parts, which are permeable, but not mentioned in the wetness indicator definition?

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Regarding definition of “ink layers”, the examiner provided two definitions conventional in the art. The examiner would like to note, that while the applicants can be their own lexicographers, the definition used by the applicants should not contradict conventional terminology.

A new set of rejections under 112, first and second paragraphs, is established in view of the amendment.

Regarding rejection over the prior art, the examiner cannot agree with the Applicant's arguments. Allan discloses an exact structure of the wetness indicator recited in claim 35, see Figure 2. The Applicant obviously refers to a different embodiment in his arguments.

The claims recited zeolite as a fluid regulating additives are rejected under 103(a). The recitation related to the zeolite pore opening size that restricts passage of a molecule larger than a water molecule is indefinite. If this is a specific pore size, it should be indicated in the claim, along with the specific zeolite that has such pore size.

Regarding two JP references, the examiner does not quite understand, why zeolite is not a water absorbing powder, when zeolites can exist as powders, granules, and pellets, and when zeolites are well known water absorbing compounds? A water absorbing powder *is* the fluid-regulating additive. What else it is? In fact, the fluid-regulating additives can be water permeable, rather than water absorbing materials, but this does not exclude the first definition.

What does it mean, that zeolites are three-dimensional structures? What are three dimensional - the molecules themselves? The forms in which zeolites are sold? The examiner did not quite understand this argument. The powder actually consists of three-dimensional particles.

The Applicant was specifically notified in the previous Office action that Deffeys was not used as a secondary reference and was not combined with the primary reference. Actually, Deffeys was used as an evidence material. Therefore, the Applicant's argument regarding Deffeys' teaching as a secondary reference is not justified.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/14/06


YELENA GAKH
PRIMARY EXAMINER